DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

February 23, 2005

WARNING LETTER NYK 2005-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis H. Eldred, Owner
Willet Dairy, LP
329 Route 34
Locke, New York 13092

Dear Mr. Eldred:

An inspection of your dairy farm operations was conducted December 28-30, 2004 by Investigator William P. Chilton. The inspection confirmed that a calf you offered for slaughter was adulterated within the meaning of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and you have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about October 18, 2004 a bull calf identified with sale tag M847 was delivered by Willet's Dairy truck to [redacted] The animal was transported to [redacted] where it was slaughtered for human food, October 20, 2004. USDA analysis of the kidney and liver tissues from this animal revealed the antibiotic drug, sulfamethazine, at levels of 6.1 ppm and 5.1 ppm respectively. No tolerance has been established for sulfamethazine in edible tissues of calves.

Our investigation found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues in edible tissues are likely to enter the food supply. For example, you lack a system for assuring: (1) that animals have been treated only with drugs which have been approved for use in those species; (2) that drugs are used in a manner not contrary to the directions contained in the labeling; and (3) that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

Our investigation revealed that you adulterated the drug Sulmet brand of sulfamethazine sodium 12.5% within the meaning of Section 501(a)(5) of the Act when you used the drug in bull calves less than one month old for which it is not approved. Furthermore, you failed to observe the required ten-day withdrawal period. The directions for approved use concerning both species and withdrawal time appear in product labeling for the drug, Sulmet.

It is your responsibility to assure your operations are in compliance with the requirements of the Act. As a dairy farmer, you are the individual who introduces (or offers for introduction) the adulterated animal into interstate commerce. It is not necessary for you to personally ship an animal into interstate commerce to be responsible for a violation of the Act.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, please state the reason for the delay and the time by which the corrections will be completed. Correspondence should be directed to Compliance Officer William J. Thompson, U.S. Food and Drug Administration, at the above address, by telephone, 716-551-4461 (3124).

Sincerely yours,

Jerome G. Woyshner
District Director